MAY 2 3 2001

K011089

510(k) Summary

Submitter Information:

Specialty UltraVision, Inc.
307 Orchard City Drive, Suite 100
Campbell, CA 95008

Contact Person: Debbie McIntire
Manager, Clinical and Regulatory Affairs

Telephone: (408) 341-0700
Fax: (408) 341-0717

Date Prepared: February , 2001

Device Name:

Common Name: Soft (Hydrophilic) Contact Lens

Trade/Proprietary Names: Specialty 42 UV (hefilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear

Specialty 42 UV Toric (hefilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear

Classification Name: Soft (Hydrophilic) Contact Lens

Device Classification: Class II (21 CFR 886.5925)

Predicate Devices:

The molded Specialty 42 and Specialty 42 Toric (hefilcon A) Soft (Hydrophilic) Contact Lenses were selected as the predicate devices.

Specialty 42 UV devices are manufactured in the same facility, under the same quality system, using the same molding, tinting, packaging and sterilization processes.

Description of Devices:

Specialty 42 UV and Specialty 42 UV Toric (hefilcon A) Soft (Hydrophilic) Daily Wear Contact Lenses are hemispherical flexible shells that cover the cornea and a portion of the adjacent sclera. Specialty 42 UV Contact Lens is available in a single vision lens design and Specialty 42 UV Toric Contact Lens is available in a back surface design. The lens material (hefilcon A) is a hydrophilic polymer of 2-hydroxyethyl methacrylate (HEMA) and n-vinyl-2-pyrrolidone (NVP) cross-linked with ethyleneglycol dimethacrylate (EGDMA), using AIBN as the initiator. The lens contains 42% water by weight. Specialty 42 UV and Specialty 42 UV Toric (hefilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear are tinted using Pigment Blue 15, ([Phthalocyaninato(2-)] copper) which is approved for coloring contact lenses under 21 CFR § 74.3045 and a UV absorbing compound has been incorporated into the lens polymer.

Comparison to Predicate Device

PARAMETER **Submission number**	**Specialty 42 UV and Specialty 42 UV Toric (hefilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear**	**Specialty 42 and Specialty 42 Toric (hefilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear** **K000376**
Material	hefilcon A	hefilcon A
Material classification	Hydrophilic Lens Group 1	Hydrophilic Lens Group 1
Indication for use	myopia, hyperopia, and astigmatism	myopia, hyperopia, and astigmatism
Water content	42%	42%
Visible light transmittance	98%	98.2%
UV transmittance	< 10%	N/A
Dk (35° C)	13.375×10^{-11}	13.333×10^{-11}
Powers	+20.00 to -20.00 Diopters	+20.00 to -20.00 Diopters
Color	blue visibility	blue visibility
Refractive index	1.416	1.42
Specific gravity	1.039	1.06
Method of manufacture	Molded	Molded

Indications for Use:

The **Specialty 42 UV (hefilcon A) Soft (Hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not-aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 diopters that does not interfere with visual acuity.

The Specialty 42 UV Toric (hefilcon A) Soft (Hydrophilic) Contact Lens is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic and/or not aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 5.00 Diopters.

The lenses may be disinfected using chemical (not heat), hydrogen peroxide, or thermal (heat) disinfecting systems. Eyecare practitioners may prescribe the lenses for daily wear and/or frequent replacement. When prescribed for a Frequent Replacement Program, the lenses may be disinfected using chemical (not heat), hydrogen peroxide, or thermal (heat) disinfecting systems.

Description of Safety and Substantial Equivalence:

A series of pre-clinical tests were performed to demonstrate the safety and effectiveness of Specialty 42 UV and Specialty 42 UV Toric (hefilcon A) Soft (Hydrophilic) Contact Lenses for Daily Wear, and to establish substantial equivalence to the predicate devices.

Results of Systemic Injection, Primary Ocular Irritation and Cytotoxicity Tests show the lenses to be non-toxic and non-irritating. Specialty 42 UV lenses were extracted and evaluated for presence of the UV blocking compound. Results showed no evidence of unsafe amounts of this compound in the extracts. Physicochemical testing of Specialty 42 UV lenses demonstrated equivalency to the predicate devices.

Conclusion:

Information submitted in the 510(k) establishes that Specialty 42 UV and Specialty 42 UV Toric (hefilcon A) contact Lenses have comparable physicochemical properties to the predicate devices and do not raise questions of safety and effectiveness. Shelf life testing has shown the lenses remain sterile and that lens properties do not change before the expiration date. Therefore, the devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 3 2001

Ms. Debbie McIntire
Manager, Clinical and Regulatory Affairs
Specialty Ultravision, Inc.
307 Orchard City Dr.
Suite 100
Campbell, CA 95008

Re: K011089
Trade Name: Specialty 42 UV (hefilcon A) Soft (hydrophilic) Contact Lens for Daily Wear and Specialty 42 UV Toric (hefilcon A) Soft (hydrophilic) Contact Lens for Daily Wear.
Regulatory Class: II
Product Code: LPL
Dated: April 6, 2001
Received: April 10, 2001

Dear Ms. McIntire:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

K011089

INDICATIONS STATEMENT

Device Names:

Specialty 42 UV (hefilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear

Specialty 42 UV Toric (hefilcon A) Soft (Hydrophilic) Contact Lens for Daily Wear

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use _____

Daniel W. C. Brown, Ph.D.

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K011089